

**UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION**

NOVARTIS VACCINES AND DIAGNOSTICS, INC., §
§

Plaintiff, §

v. §

CIVIL ACTION NO. 2:07-CV-507

HOFFMANN-LA ROCHE INC., §
ROCHE LABORATORIES INC., §
ROCHE COLORADO CORP., §
TRIMERIS, INC., and §
F. HOFFMANN-LA ROCHE LTD, §

Defendants. §

**REPLY IN SUPPORT OF DEFENDANTS HOFFMANN-LA ROCHE INC.,
ROCHE LABORATORIES INC. AND TRIMERIS, INC. TO TRANSFER PURSUANT
TO 28 U.S.C. §§ 1404 AND 1406 OR, IN THE ALTERNATIVE, TO DISMISS TRIMERIS**

Novartis's Response focuses almost exclusively on Trimeris and its alleged "contacts" with Texas (with virtually no mention of *any* contacts with the Eastern District of Texas) that allegedly make jurisdiction proper. Novartis fails to identify a single witness, document, or other contact within this District to rebut Defendants' strong showing that this case would be more conveniently tried in the Eastern District of North Carolina ("EDNC"). Defendants maintain that this action should be transferred to the EDNC. However, if transfer is denied, this Court should dismiss Trimeris from this action under Federal Rules of Civil Procedure 12(b)(2) and (3).

I. THE COURT SHOULD TRANSFER THE ACTION TO THE EDNC UNDER SECTIONS 1404 AND 1406

Novartis does not dispute that the EDNC is a proper transferee forum, in which this case could have been brought.¹ Because the private and public factors favor transfer, this Court need not determine whether jurisdiction over Trimeris is appropriate, but rather should transfer the action to the EDNC.

A. The Private Interest Factors Favor Transfer

1. Novartis' Contention That The Location Of Sources Of Proof Is Irrelevant Is Wrong As A Matter Of Law

Novartis does not dispute that relevant sources of proof are located in the EDNC. Rather, Novartis attempts to denigrate this factor by claiming that documentary sources of proof are readily converted into electronic form and therefore their location is not an issue to be considered. Novartis' contention is not supported by law. District Courts in the Fifth Circuit have not abandoned consideration of the relative ease of access to sources of proof, even though electronic information may have lessened the inconvenience for the parties. *United States v. Midwest Transport, Inc.*, No. 3:07-CV-1736-M, 2008 WL 1805766, at *3 (N.D. Tex. Apr. 22, 2008); *RLI Ins. Co. v. Allstate County Mutual Ins. Co.*, No. 3:07-CV-1256-M, 2007 WL

¹ Novartis' Response ignores that the Roche Defendants also have moved to transfer. It is uncontested that the EDNC is a proper transferee forum as to the Roche Defendants as well as Trimeris.

2201976, at *2 (N.D. Tex. May 28, 2008). Accordingly, this factor weighs strongly in favor of transfer.

2. *Novartis Cannot Deny That Compulsory Process Is Not Available For Important Witnesses Identified By Defendants And Has Identified No Witnesses In The Eastern District of Texas*

Novartis fails to identify a single witness who resides in the Eastern District of Texas, and seeks to brush aside the important third party witnesses located in the EDNC. As set forth in their declarations, Drs. Bolognesi, Greenberg, Bray, and Smiley are all fact witnesses who were deeply involved in the development and testing of Fuzeon. Their proposed testimony relates to key defenses and counterclaims in the case, as identified in the Moving Brief at pp 2-3, including: (1) non-infringement; (2) invalidity under 35 U.S.C. § 112 and for failure to enable the synthesis of peptides as large as those encompassed by the claims; (3) damages; and (4) that the injunction sought by Novartis would be against the public interest because it would lead to the death of end-stage AIDS patients relying on Fuzeon. Novartis ignores the Moving Brief in asserting that “it is not clear that any of these witnesses have meaningful testimony” or that their testimony would only “relat[e] to an enablement defense.” Response at 13.

The substantial inconvenience for such “key fact witnesses” is the most important factor the court must consider in determining whether transfer is warranted. *Orica Explosives Tech., Pty., Ltd. v. Austin Powder Co.*, No. 2:06-CV-450, 2007 WL 1115238, at *3 (E.D. Tex. Apr. 13, 2007). Further, the convenience of non-party witnesses weighs more heavily in favor of transfer than the convenience of party witnesses. *Id.* The four identified key fact witnesses are former Trimeris officers or employees and are no longer under the control of any of the parties.² All of

² That Defendants were able to secure declarations by these percipient third party witnesses is no guarantee that they could also secure their attendance at trial. The commitment necessary to travel to and from Marshall, TX to attend trial far outstrips the time needed to prepare declarations or provide live testimony in North Carolina. Nor is this factor dispelled by Novartis’ assertion that testimony from experts is often presented by videotaped deposition. These are fact witnesses, for whom videotaped depositions would not be an adequate substitute: “Certainly to fix the place of trial at a point where litigants cannot compel personal attendance and may be forced to try their cases on deposition, is to create a condition not satisfactory to

these key third party witnesses could be subpoenaed for trial in the EDNC, but not in the Eastern District of Texas. The availability and convenience of the witnesses therefore strongly favors transfer.

3. *The Costs Of Attendance For Willing Witnesses Would Be Far Greater in the Eastern District of Texas*

Novartis attempts to discount the inconvenience to potential witnesses of a trial in Texas by claiming that preparation can occur where a witness resides and that trial time is not significant. Novartis ignores the actual time and cost that travel entails, as well as meals, lodging, and missed days from work. Defendants' witnesses will save travel expenses and prolonged absences from work if the case is transferred to the EDNC, while California-based Novartis will incur travel expenses regardless whether the litigation proceeds in Texas or California. The travel time to fly from San Francisco, CA, where Novartis is located, to Raleigh, NC (approximately 6.5 hours) is no greater than the total travel time between San Francisco and Marshall, TX (which requires a 3.5 hour flight to Dallas, followed by a 3 hour drive to Marshall). Novartis has not made any demonstration that North Carolina is a less convenient forum for its witnesses than Texas, nor could it. This factor strongly favors transfer.

B. The Public Interest Factors Support Transfer

1. *There Is Less Court Congestion In The EDNC*

The most recent Federal Court Management Statistics clearly show that the EDNC (10th fastest docket, 16.5 month average time to trial) is less congested than the Eastern District of Texas (14th fastest docket, 18.0 month average time to trial). Novartis asks the Court to ignore these statistics on the grounds that "they are not specific to patent infringement cases." Response at 15. But these are precisely the statistics that courts use in evaluating transfer of patent cases. *See Hanby v. Shell Oil Co.*, 144 F. Supp. 2d 673, 677 (E.D. Tex. 2001) (relying on general caseload statistics and finding that similarity of caseloads supported transfer of patent action). Moreover, a search of active patent cases shows that the judges in this District are far more

court, jury, or most litigants." *Empty Barge Lines II, Inc. v. Fisher*, 441 F. Supp. 2d 786, 796 (E.D. Tex. 2006) (quoting *Gulf Oil Corp. v. Gilbert*, 330 U.S. 501, 511 (1947)).

heavily burdened with patent cases than in the EDNC. *See* Exhibit A (Courtlink search, showing 16 active patent cases in the EDNC compared with 485 active patent cases in this District). This factor favors transfer.

2. *There Is No Localized Interest in the Eastern District of Texas And Strong Interest in the EDNC*

Fuzeon was invented and developed in the EDNC, where it is also sold and used. No research or development occurred in the Eastern District of Texas, nor in actuality is Fuzeon widely used here. A forum's localized interest based merely on nationwide sales of an allegedly infringing product creates only an attenuated relationship compared to that of a forum where the product was invented and developed. *Amini Innovation Corp. v. Bank & Estate Liquidators, Inc.*, 512 F. Supp. 2d 1039, 1046 (S.D. Tex. 2007). In weighing local interest this court should take into account the prominent industries of the respective fora. *See Network-1 Security Solutions, Inc. v. D-Link Corp.*, 433 F. Supp. 2d 795, 801 (E.D. Tex. 2006) (factoring technology industry in Plano, TX into analysis of local interest). The biotech industry plays a prominent role in the EDNC, whereas this District is known for other industries. This factor favors transfer.

3. *Novartis Is Wrong To Contend That The EDNC Is Less Capable Of Handling Patent Cases Than The Eastern District Of Texas*

Both the Eastern District of Texas and the EDNC courts are familiar with the issues of patent law. There is no evidence that the EDNC is any less capable of handling patent cases than the Eastern District of Texas. In fact, the EDNC has extensive experience in patent litigation in the biotech and pharmaceutical fields, including litigation involving Sandoz – the generics division of Novartis. *See* Exhibit B, 2007 Novartis Annual Report at 6; *Sepracor Inc. v. Sandoz, Inc.*, No. 4:08-CV-89 (E.D.N.C. filed June 12, 2008); *Wyeth v. Sandoz, Inc.*, No. 5:07-CV-234 (E.D.N.C. filed June 22, 2007); *Wyeth v. Osmotica Pharma. Corp.*, No. 7:07-CV-67 (E.D.N.C. filed Apr. 20, 2007); *Torpharm Inc. v. Novopharm, Ltd.*, No. 5:97-CV-968-BO(3), 1998 WL 34137163 (E.D.N.C. May 26, 1998); *Cardiovascular Diagnostics v. Boehringer Mannheim Corp.*, 985 F. Supp. 615 (E.D.N.C. 1997); *Glaxo, Inc. v. Novopharm, Ltd.*, 931 F. Supp. 1280 (E.D.N.C. 1996); *Burroughs Wellcome Co. v. Barr Lab.*, 828 F. Supp. 1208 (E.D.N.C. 1993).

Novartis purports to distinguish the Eastern District of Texas by noting that it has adopted Local Patent Rules, but this is no distinction between the districts: the EDNC likewise has adopted Local Patent Rules (attached as Exhibit C).

4. *Transfer Obviates Jurisdictional Difficulty And Avoids Unnecessary Duplicative Litigation*

Transferring this case would render it unnecessary to resolve the issue of personal jurisdiction over Trimeris. “A transfer, obviating a jurisdictional difficulty, has been found to serve the interests of justice within the meaning of that language in § 1404(a).” *Kahhan v. City of Fort Lauderdale*, 566 F. Supp. 736, 740 (E.D. Pa. 1983). Moreover, if the Court finds that Trimeris must be dismissed or transferred to the EDNC (*see* Point II *infra*), failure to transfer the Roche Defendants would raise the prospect of two litigations in different district courts involving precisely the same issues. This would represent “the wastefulness of time, energy and money that Section 1404(a) was designed to prevent.” *Continental Grain Co. v. Barge FBL-585*, 264 U.S. 19, 26 (1960). This factor favors transfer.

5. *The Center of Gravity Test Applies and Favors Transfer*

Novartis’ argument that, in general, there is not an identifiable “center of gravity” in patent cases is not true. Courts in the Fifth Circuit have determined the center of gravity in patent cases and considered that location in their transfer analysis. *Amini*, 512 F. Supp. 2d at 1044; *Baxa Corp. v. ForHealth Techs., Inc.*, No. 3:05-CV-2274-D, 2006 WL 680503 (N.D. Tex. Mar. 15, 2006); *Minka Lighting, Inc. v. Trans Globe Imports, Inc.*, No. 3:02-CV-2538, 2003 WL 21251684 (N.D. Tex. May 23, 2003).

Nor is the center of gravity analysis synonymous with the center-of-geography as Novartis implies. Rather, it is based on the location of the accused product’s development, testing, research, and production. *Minka*, 2003 WL 21251684, at*3; *accord Amini*, 512 F. Supp. 2d at 1044; *Baxa*, 2006 WL 680503, at *2. Here, the research, discovery, and pre-clinical testing of Fuzeon occurred in the EDNC. In intellectual property cases, which “often focus on the activities of the alleged infringer, its employees, and its documents; [] the location of the alleged

infringer's principal place of business is often the critical and controlling situation in adjudicating transfer of venue motions." *Amini*, 512 F. Supp. 2d at 1044 (quoting *Houston Trial Reports, Inc. v. LRP Publ'ns, Inc.*, 85 F. Supp. 2d 663, 668 (S.D. Tex. 1999)); accord *Minka*, 2003 WL 21251684, at *3. Although subsequent development and commercialization occurred elsewhere, the center of gravity is undoubtedly in the EDNC. The center of gravity favors transfer.

II. EXERCISE OF JURISDICTION OVER TRIMERIS IS NOT APPROPRIATE AND VENUE IS IMPROPER AS TO TRIMERIS

Respectfully stated, this Court does not have jurisdiction over Trimeris, nor is venue proper as to Trimeris. Novartis sprinkles various statements about Trimeris and its activities throughout its Response which are alleged to support jurisdiction and venue over Trimeris; however, these few anecdotal items are insufficient to establish jurisdiction. Rather, the facts demonstrate why the exercise of jurisdiction over Trimeris is not appropriate.

A. Mere Existence of the Fuzeon Website Is Not Sufficient to Establish Minimum Contacts

The mere existence of a Fuzeon website bearing Trimeris' name is not sufficient to establish minimum contacts with the forum. The Fuzeon website is not "interactive" and does not permit a person in Texas, or anywhere else, to order Fuzeon through an Internet sale. *See* Exhibit D, Graham Decl., ¶ 3; Exhibit E, Klein Decl., ¶ 3. Novartis relies on a strained definition of "interactive" that does not comport with the accepted use of the term, as an "interactive" website is generally understood to be a website that allows consumers in the United States, and more particularly within the District, to purchase a defendant's products. *See, e.g., Litepanels, LLC v. Gekko Tech., Ltd.*, Case No. 2:06-CV-167, 2006 U.S. Dist. LEXIS 75017, at *5-*6 (E.D. Tex. October 16, 2006). An interactive website may satisfy the minimum contacts requirement when "[a] website . . . [allows owners to] engage in repeated online contacts with forum residents through the site." *AdvanceMe, Inc. v. Rapidpay LLC*, 450 F. Supp. 2d 669, 673 (E.D. Tex. 2006) (citing *Revell v. Lidov*, 317 F.3d 467, 470 (5th Cir. 2002)). The Fuzeon website fails to meet these basic requirements to establish minimum contacts. It is undisputed that no sales

have been made through the Fuzeon website. *See* Exhibit D, ¶ 3; Exhibit E, ¶ 3. Trimeris has not and does not engage in business transactions or enter into contracts, relating to Fuzeon, over the Internet with Texas residents. Exhibit D, ¶ 5. A Fuzeon website bearing Trimeris' name that may be accessed in the District cannot form the basis for jurisdiction over Trimeris.

Moreover, courts have found that even for a website with a high level of commercial activity – which the Fuzeon website does not have – an entity must be “sufficiently related to or responsible for the website to have purposefully availed itself of the protections of the forum state by directing activities towards Texas.” *See, e.g., Phonetel Commc'ns, Inc. v. U.S. Robotics Corp.*, Civil Action No. 4:00-CV-1750-R, 2001 U.S. Dist. LEXIS 7233, at *11 (N.D. Tex. June 1, 2001). Novartis cannot demonstrate that Trimeris participates in a substantive manner, other than allowing its logo to be used, with the Fuzeon website. Exhibit D, ¶ 4. Trimeris does not contribute any substance to the Fuzeon website and has not done so since at least December 2006. *Id.*; *see also* Exhibit E, ¶ 4. Trimeris is not involved in generating and/or maintaining information contained on the Fuzeon website. *Id.* Because of the nature and quality of Trimeris' involvement with the website, combined with the inability of potential customers to purchase Fuzeon through the website, the exercise of jurisdiction over Trimeris is not proper.

B. The Recent Clinical Trial Has Been Executed by Roche With Minimal Connection to the State of Texas And No Connection to This District

Novartis emphasizes in its Response that the NIH website shows at least one Fuzeon clinical trial remains active. The latest Fuzeon clinical trial is called the AMICI trial. *See* Exhibit D, ¶ 9; Exhibit F, Guittari Decl., ¶ 3. The AMICI trial has been closed to enrollment as of March 25, 2008. Exhibit F, ¶ 5. The AMICI trial enrolled a small number of patients in Texas with a total patient enrollment of 5 subjects across three Texas sites. *Id.* ¶¶ 4-5. None of the five designated sites in Texas, and particularly, none of the sites enrolling patients in Texas were located in the Eastern District of Texas. *Id.* ¶ 4. This limited extent to which clinical trials took place in the entire State of Texas hardly rises to the level of substantial contacts to support an exercise of personal jurisdiction by this Court. Nor do these contacts support venue here,

given that Novartis must concede that none of these clinical trials took place in the Eastern District of Texas. *See, e.g., Surgical Laser Techs., Inc. v. C.R. Bard, Inc.*, 921 F. Supp. 281, 284 (E.D. Pa. 1996).³

Further, Roche was responsible for execution of the protocol for the AMICI trial. *See* Exhibit D, ¶ 9; Exhibit F, ¶ 3. While Trimeris was involved in development of the protocol for the AMICI trial, Trimeris' involvement in the AMICI trial ended as of November 2007. *Id.* Trimeris was identified as a collaborator for this clinical trial because half of the costs of the trial were deducted as costs from its account. Exhibit D, ¶ 9. Except for indirect financial support, Trimeris did not direct or participate in the execution of the protocol for the AMICI trial. *Id.* Novartis also emphasizes language from the Roche-Trimeris Agreement discussing the Joint Steering Committee ("JSC") establishing a "Development Project Team" to implement the "Development Program." However, the "Development Program" merely refers to the clinical trials conducted as part of the FDA approval process. Exhibit D, ¶ 8. Upon execution of the Roche-Trimeris agreement, Roche assumed the principal role with respect to the staffing, management and direction of the pivotal Phase III clinical trials for Fuzeon. *Id.* Trimeris' activities with respect to the Development Program were largely ancillary and supportive to the Roche contribution. *Id.* Also, as Novartis concedes, Roche managed the FDA approval process and consequently controlled the development of Fuzeon in New Jersey. *See* Response at 16.

C. Nationwide Sales and A Single Sale Within The District Does Not Establish Jurisdiction or Venue

Novartis cites to no case supporting the contention that the nationwide sale of an accused product by a product licensee (Roche) solely at the direction and control of the vendor (Roche) subjects Trimeris to the jurisdiction of this Court. In desperation, Novartis relies on a receipt for one purchase of Fuzeon in the District to allege this represents a pattern of sales in Texas for five years. Whether a single sale of Fuzeon by some entity (not even confirmed to be Roche) in the

³ The court held that clinical trials in Pennsylvania combined with visits to Pennsylvania, a contract leading to sales in Pennsylvania, and some employee presence in Pennsylvania were insufficient to establish general jurisdiction. *See Surgical Laser Techs.*, 921 F. Supp. at 284.

Eastern District of Texas might create jurisdiction over the vendor, it does not demonstrate that Trimeris (or Roche for that matter) have an “established distribution channel” within the Eastern District of Texas sufficient to establish jurisdiction under a stream of commerce theory. *See Beverly Hills Fan Co. v. Royal Sovereign Corp.*, 21 F.3d 1558, 1566 n.15 (Fed. Cir. 1994).

D. Trimeris Is Not Subject to Jurisdiction or Venue Merely Because of Entering Into a Royalty Arrangement With Roche

Novartis also would have this Court conclude that because Roche may generally conduct business in the Eastern District of Texas, then Trimeris also is subject to the jurisdiction and venue of the Court merely by having entered into a license agreement with Roche. Roche has a license to manufacture and market Fuzeon, and the agreement between Roche and Trimeris is simply an agreement providing for the method of how Trimeris receives payments. Exhibit D, ¶ 6; Exhibit E, ¶ 5. Novartis argues that the arrangement between Roche and Trimeris is akin to that discussed in *Breckenridge*; however, the facts involved in the present action are much closer to the facts discussed in *Red Wing Shoe Co., Inc. v. Hockerson-Halberstadt, Inc.*, 148 F.3d 1355 (Fed. Cir. 1998). In *Red Wing Shoe*, the Federal Circuit concluded that “doing business with a company that does business in [the forum state] is not the same as doing business in [the forum state].” *Id.* at 1361. To think otherwise “would subject a defendant to nationwide personal jurisdiction if it decides to do business with a company that does business nationwide.” *Id.* The Federal Circuit also confirmed that there is no personal jurisdiction over an out-of-state defendant who merely receives royalty income from its licensees for sales made in the forum state. This is true when the defendant, like Trimeris here, does not exercise control over the sales activities of its licensees and had no dealings with its licensees in the forum. The facts of *Red Wing Shoe* are directly applicable to the facts of the present action.

While Fuzeon, the product marketed and manufactured by Roche, would not have come into existence without Trimeris’ important work performed long before the patent-in-suit issued, this fact alone does not mean that the exercise of jurisdiction or venue over Trimeris is proper. Similarly, sharing of expenses does not support jurisdiction or venue over Trimeris. While

Trimeris receives revenues based on the costs and profits related to Fuzeon, Trimeris does not have control of the manufacturing process/schedule and does not currently provide substantial input regarding the marketing of Fuzeon. Exhibit D, ¶ 7; Exhibit E, ¶ 6. Rather, as addressed in Defendants' Moving Brief, Trimeris is a passive recipient of payments and has no involvement with Fuzeon's manufacture, sale or distribution in general and certainly not within Texas or the Eastern District of Texas so as to make the exercise of jurisdiction proper.

III. CONCLUSION

For all the foregoing reasons and for the reasons set forth in Defendants' Moving Brief, Trimeris and the Roche Defendants request that the action be transferred to the EDNC, or in the alternative, that Trimeris be dismissed for lack of personal jurisdiction and improper venue.

Respectfully submitted this 1st day of August, 2008,

/s/ Robert M. Chiaviello, Jr.

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that all counsel of record who are deemed to have consented to electronic service are being served with a copy of this document via the Court's CM/ECF system per Local Rule CV-5(a)(3).

/s/ Robert M. Chiaviello, Jr.

Robert M. Chiaviello, Jr.